

SUPPORT FOR THE AMENDMENTS

Claims 3, 4, 11-13, 27-29, and 33-58 were previously canceled.

Claim 15 is canceled herein.

Claims 1 and 30-32 have been amended.

The amendment to Claims 1 and 30-32 is supported by original Claims 1 and 15.

Additional support for the amendment to Claim 1 is provided by the specification as originally filed, for example, at Example 2.

No new matter has been added by the present amendments.

REMARKS

Claims 1, 2, 5-10, 14, 16-26, and 30-32 are pending in the present application.

At the outset, Applicants wish to thank Examiner Roberts for the helpful and courteous discussion with their undersigned Representative on June 2, 2010. During this discussion various amendments and arguments in traverse of the outstanding rejections were discussed. The content of this discussion is reflected in the following comments.

Reconsideration of the outstanding rejections is requested.

The rejection of Claims 1, 2, 5-10, 14, 16-23, and 30-32 under 35 U.S.C. §103(a) over Kobayashi (JP 58088323), is respectfully traversed, but nonetheless obviated by amendment.

In the outstanding Office Action, the Examiner has now extended the search to embrace “abnormal gastric motion” and has rejected the claims over Kobayashi (JP 58088323). Applicants submit that the present invention is distinct from Kobayashi in that the claimed invention is specific to stress-induced abnormal gastric motion and the patient subset to be treated are those with a specific, recognized need for such treatment (*Jansen v. Rexall Sundown Inc.*, 342 F.3d 1329, 1332, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003)). Even assuming that infantile anorexia, diarrhea, and dyspepsia of protein would be considered “abnormal gastric motion”, there is nothing in Kobayashi to disclose or suggest that these disorders have anything to do with stress. If

Even with the foregoing, Applicants submit that, as was the case previously, the Examiner alleges that such a method would be obvious in view of the disclosure of Kobayashi or at the very least it would have been within the general abilities of the artisan. In an attempt to support this allegation, the Examiner cites *KSR v. Teleflex* and merely makes

a general assertion that there is a market pressure to find treatments to treat stress induced lesions.

The Examiner's allegations are without merit and still fail to support a *prima facie* case of obviousness over Kobayashi. At best, the modifications in the cited references to arrive at the specifically claimed combination of components and treatment method amount to nothing more than an "invitation to experiment" or "obvious to try"; however, "obvious to try" has long been held *not* to constitute obviousness. *In re O'Farrell*, 7 USPQ2d 1673, 1680-81 (Fed. Cir. 1988). A general incentive does not make obvious a particular result, nor does the existence of techniques by which those efforts can be carried out. *In re Deuel*, 34 USPQ2d 1210, 1216 (Fed. Cir. 1995).

KSR International Co. v. Teleflex Inc., 550 U.S. ___, 82 USPQ2d 1385 (2007) does not eliminate the "obvious to try is not obvious" standard, as it clearly states that "obvious to try" may constitute obviousness, but only under certain circumstances. Specifically, *KSR* stated that the fact that a claimed combination of elements was "obvious to try" might show that such combination was obvious under 35 U.S.C. § 103, since, if there is design need or market pressure to solve problem, and there are finite number of identified, predictable solutions, person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation. However, the Examiner offers nothing more than blanket assertions but fails to show how these factors apply and whether there would be such an expectation or anticipated success.

Further, the claims require that lysine is in a lysine/glutamic acid salt complex. Kobayashi disclose that the free amino acids are used, but fails to disclose that lysine is in salt form with glutamic acid. The Examiner alleges that Kobayashi disclose lysine glutamate

(i.e., a lysine salt) and further discloses that glutamic acid may be used with lysine. Thus, the Examiner alleges that Kobayashi disclose a salt form of lysine and that glutamic acid is used together with the salt form of lysine. At no point does Kobayashi disclose or suggest a specific lysine/glutamic acid salt complex. Thus, Applicants maintain that the present invention is not obvious in view of Kobayashi.

Nonetheless, to expedite examination of the present application, Applicants have amended Claim 1 to limit the claimed method to “[a] method of ameliorating, progress blocking, or therapeutically treating irritable bowel syndrome comprising administering to a subject in need thereof an effective amount of a pharmaceutical composition comprising lysine and arginine, wherein the lysine is in a salt form with glutamic acid.” (Claim 1) Applicants submit that the Kobayashi fails to disclose or suggest “a method of ameliorating, progress blocking, or therapeutically treating irritable bowel syndrome as presently claimed. Thus, Applicants submit that such a method would not be obvious.

Withdrawal of this ground of rejection is requested.

Applicants submit that the present application is now in condition for allowance.
Early notification of such action is earnestly solicited.

Respectfully submitted,

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